



Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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### Complete If Known

Application Number	09/919,278 Conf. No. 4703
Filing Date	July 31, 2001
First Named Inventor	Herm Snyder
Art Unit	1615
Examiner Name	Yebassa, Desta Letta
Attorney Docket Number	NEKT/0002

Sheet 1 of 4

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
[Signature]	1	US- 2002/0071871	08/13/2002	Snyder et al.	
	2	US- 2002/0081266	08/27/2002	Woolfe et al.	
	3	US- 2002/0175225	11/28/2002	Boersen et al.	
	4	US- 2003/0124183	07/03/2003	Snyder et al.	
	5	US- 2003/0203036	10/30/2003	Gordon et al.	
	6	US- 3790079	02/05/1974	Berglund et al.	
	7	US- 3825188	07/23/1974	Doering	
	8	US- 4035317	07/12/1977	Gershberg	
	9	US- 4052255	10/04/1977	Hackbarth et al.	
	10	US- 4221339	09/09/1980	Yoshikawa	
	11	US- 4486435	12/04/1984	Schmidt et al.	
	12	US- 4540602	09/10/1985	Motoyama et al.	
	13	US- 4590206	05/20/1986	Forrester et al.	
	14	US- 4702799	10/27/1987	Tuot	
	15	US- 4721709	01/26/1988	Seth et al.	
	16	US- 4748034	05/31/1988	de Rham	
	17	US- 4784878	11/15/1988	Haak	
	18	US- 4794167	12/27/1988	Lindner et al.	
	19	US- 4818424	04/04/1989	Evans et al.	
	20	US- 4835187	05/30/1989	Reuter et al.	
	21	US- 4952402	08/28/1990	Sparks et al.	
	22	US- 5000888	03/19/1991	Kilbride, Jr. et al.	
	23	US- 5009367	04/23/1991	Nielsen	
	24	US- 5017372	05/21/1991	Hastings	
	25	US- 5026550	06/25/1991	Aeschbach et al.	
	26	US- 5084501	11/12/1991	Boersen	
	27	US- 5221731	06/22/1993	Weymans et al.	
	28	US- 5279708	01/18/1994	Wood et al.	
	29	US- 5336837	08/09/1994	Tan et al.	
	30	US- 5376386	12/27/1994	Ganderton et al.	
	31	US- 5518709	05/21/1996	Sutton et al.	
	32	US- 5542935	08/06/1996	Unger et al.	
	33	US- 5580856	12/03/1996	Prestrelski et al.	
	34	US- 5609919	03/11/1997	Yuan et al.	
	35	US- 5628937	05/13/1997	Oliver et al.	
	36	US- 5648096	07/15/1997	Gander et al.	
	37	US- 5651990	07/29/1997	Takada et al.	
	38	US- 5716558	02/10/1998	Nielsen et al.	
	39	US- 5723269	03/03/1998	Akagi et al.	
	40	US- 5741478	04/21/1998	Osborne et al.	
	41	US- 5776491	07/07/1998	Allen, Jr. et al.	
	42	US- 5800598	09/01/1998	Cheln et al.	
	43	US- 5807576	09/15/1998	Allen, Jr. et al.	
	44	US- 5855913	01/05/1999	Hanes et al.	
	45	US- 5874084	02/23/1999	Edwards et al.	
	46	US- 5957848	08/28/1999	Sutton et al.	
	47	US- 5984418	10/12/1999	Jaeger et al.	
	48	US- 5970974	01/26/1999	Van Der Linden et al.	
	49	US- 5972388	10/28/1999	Sakon, et al.	

50	US- 5976574	11/02/1999	Gordon	
51	US- 6015548	01/18/2000	Sutton et al.	
52	US- 6022525	02/08/2000	Sutton et al.	
53	US- 6077543	08/20/2000	Gordon et al.	
54	US- 6116516	09/12/2000	Ganan-Calvo	
55	US- 6136295	10/24/2000	Edwards et al.	
56	US- 6149941	11/21/2000	Schwarz et al.	
57	US- 6153129	11/28/2000	Herbert et al.	
58	US- 6174469	01/16/2001	Ganan-Calvo	
59	US- 6197835	03/06/2001	Ganan-Calvo	
60	US- 6223455	05/01/2001	Chickering, III et al.	
61	US- 6254854	07/03/2001	Edwards et al.	
62	US- 6290991	09/18/2001	Roser et al.	
63	US- 6308434	10/30/2001	Chickering, III et al.	
64	US- 6316029	11/13/2001	Jain et al.	
65	US- 6331310	12/18/2001	Roser et al.	
66	US- 6352209	03/05/2002	Skeath et al.	
67	US- 6365190	04/02/2002	Gordon et al.	
68	US- 6451349	09/17/2002	Robinson et al.	
69	US- 6503480	01/07/2003	Edwards et al.	
70	US- 6565885	05/20/2003	Tarara et al.	
71	US- 6572893	06/03/2003	Gordon et al.	
72	US- 6592904	07/15/2003	Platz et al.	
73	US- 6656492	12/02/2003	Kajiyama et al.	
74	US- 6660382	12/09/2003	Nouri et al.	
75	US- 6884408	04/26/2005	Rabinowitz et al.	
76	US- 6383810	05/07/2002	Fike et al.	
77	US- 4127235	11/28/1978	Klailest et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> - Number <sup>3</sup> - Kind Code <sup>4</sup> (if known)				
LW	78	EP0122036	10-17-1984	TEIJIN LTD (JP)		
	79	EP0344375	12-06 -1989	DAMROW CO INC (US)		
	80	EP0360340	03-28-1990	AKZO NV (NL)		
	81	EP0383569	08-22-1990	PAFRA LTD (GB)		
	82	EP0408801	01-23-1991	OGAWARA KAKOKI KK (JP)		
	83	EP0464171	01-08-1992	NAT RES DEV (GB)		
	84	EP0611567	08-24-1994	TEIJIN LTD (JP)		
	85	EP0072046	02-16-1983	FISONS PLC (GB)		
	86	EP681843	11-15-1995	ANDARIS LTD (GB)		
	87	EP748751	02-27-1995	TSI INC (US)		
	88	EP899017	03-03-1999	UNIV SEVILLA (ES)		
	89	EP972526	01-19-2000	QUADRANT HEALTHCARE UK LTD (GB)		
	90	GB 2105189	03-23-1983	FISONS PLC (GB)		
	91	UK 473471	10-13-1937	EMIL KIRSCHBAUM		
	92	UK 621785	04-20-1949	TECO SA		
	93	WO 00/13668	03-16-2000	QUADRANT HEALTHCARE UK LIMITED (GB); et al.		
	94	WO 00/66256	11-09-2000	ACUSPHERE INC (US)		
	95	WO 01/03673	01-18-2001	QUADRANT HOLDINGS CAMBRIDGE (GB)		
96	WO 01/13885	03-01-2001	NORTON HEALTHCARE LTD (GB) et al			
97	WO 01/15664	03-08-2001	BRADFORD PARTICLE DESIGN PLC (GB)			
98	WO 01/87278	11-22-2001	QUADRANT HEALTHCARE UK LTD (GB) et al.			
99	WO 02/078675	10-10-2002	ADVANCED INHALATION RES INC (US)			
LW	100	WO 02/15876	02-28-2002	QUADRANT HEALTHCARE UK LTD (GB) et al.		

101	WO 02/15880	02-28-2002	MERCK PATENT GMBH (DE);
102	WO 03/000202	2003-01-03	ADVANCED INHALATION RES INC (US)
103	WO 88/07870	10-20-1988	CARBOMATRIX AB (SE)
104	WO 90/11139	10-04-1990	UNION CARBIDE CHEM PLASTIC (US)
105	WO 94/08627	04-28-1994	DELTA BIOTECHNOLOGY LTD (GB) et al.
106	WO 95/13864	05-26-1995	NIRO HOLDING AS (DK);
107	WO 95/23613	09-08-1995	GENENTECH INC (US)
108	WO 95/31479	11-23-1995	INHALE THERAPEUTIC SYST (US);
109	WO 96/05809	02-29-1996	QUADRANT HOLDINGS CAMBRIDGE (GB) et al.
110	WO 96/09814	04-04-1996	ANDARIS LTD (GB)
111	WO 96/11580	04-25-1996	WATERFORD CREAMERY LTD (IE) et al.
112	WO 96/32149	10-17-1996	INHALE THERAPEUTIC SYST (US)
113	WO 97/28788	08-14-1997	QUADRANT HOLDINGS CAMBRIDGE (GB) et al.
114	WO 97/36574	10-09-1997	GLAXO GROUP LTD (GB) et al.
115	WO 98/01228	01-15-1998	SPRAYCHIP SYSTEMS CORP (US) et al.
116	WO 98/31346	07-23-1998	MASSACHUSETTS INST TECHNOLOGY (US) et al.
117	WO 98/36888	08-27-1998	NANOCHEM RES LLC (US)
118	WO 99/16419	04-08-1999	ALLIANCE PHARMA (US) et al.
119	WO 99/16422	04-08-1999	ALLIANCE PHARMA (US) et al.
120	WO 99/17742	-04-15-1999	ELAN CORP PLC (IE) et al.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 4 of 4

**Complete if Known**

Application Number	09/919,278 Conf. No. 4703
Filing Date	July 31, 2001
First Named Inventor	Herm Snyder
Art Unit	1615
Examiner Name	Yebassa, Desta Letta
Attorney Docket Number	NEKT/0002

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
lu	121	JULIENNE ET AL., "Preparation of Poly (D, L-Lactide/Glycolide) Nanoparticles of Controlled Particle Size Distribution: Application of Experimental Designs," Drug Development and Industrial Pharmacy, Vol. 18, No. 10, p. 1063-1077 (1992).*	
	122	BLOCH et al., "Dispersions of Hydrochlorothiazide and Chlorhalidone in Pentaerythritol," Pharm. Acta. Helv. (1983), 58 (1), p. 14-22.*	
	123	BOHNET, Matthias, "Calculation and Design of Gas/Solid-Injectors," Powder Tech, 1984, pp. 302-313.*	
	124	CARPENTER, John F. et al., "Modes of Stabilization of a Protein by Organic Solutes During Desiccation," Cryobiology, 1988, Volume 25, pp. 459-470.*	
	125	HE ET AL., "Chitosan Microspheres Prepared by Spray Drying," International J. of Pharm. (Amsterdam), Vol. 187, No.1, o. 53-65*	
	126	HINO ET AL., "Development of a new type nozzle and spray-drier for industrial production of fine powders", European J. of Pharmaceutics and Biopharmaceutics (2000), Vol. 49, pp. 79-85.*	
	127	MASTERS, "The Process Stages of Spray Drying: Atomization", Spray Drying Handbook, pp. 230-247.*	
	128	MUMENTHALER et al., "Feasibility Study on Spray-Drying Protein Pharmaceuticals: Recombinant Human Growth Hormoine and Tissue-Type Plasminogen Activator," Pharm Res. (1994), 11(1): P 12-20. *	
	129	Partial EP Search Report dated January 4, 2006 for Application No. 97926420.7 (NEKT/0013) *	
lu	130	RANDOLPH ET AL., "Sub-micrometer-sized biodegradable particles of poly(L-lactic acid) via the gas antisolvent spray precipitation process," Biotechnol. Prog, Vol. 9, No.4, o. 429-435 (1993).*	

Examiner Signature		Date Considered	10/51/06
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